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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,568	05/15/2001	Samuel Bogoch	9425/46702	8438

7590 02/13/2006

KENYON & KENYON
Suite 700
1500 K Street, N.W.
Washington, DC 20005

EXAMINER	
SAUNDERS, DAVID A	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 02/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/854,568	BOGOCH, SAMUEL	
	Examiner	Art Unit	
	David A. Saunders, PhD	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2005 and 18 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *6-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Amendments of 8/15/05 and 11/18/05 have been entered. Claims 1-13 are pending. Claims 1-5 are under examination.

The substitute specification of 14 pages, filed on 8/15/05, has been approved for entry.

Regarding the drawings, it is to be noted that instant Fig. 1, in black and white, has been printed in applicant's US PGPUB 2002/0045187; therefore the drawings are considered printable and are not objected to. As far as the examiner can determine from the description of Fig. 1, there are no images showing two colors of staining; therefore, submission of colored drawings is optional. Applicant is reminded of the requirement to file a petition under 37 CFR 1.84(a)(2) with any color Figs.

The amendment/response has overcome previously stated issues as follows:
The objection to the oath.
The objection to specification page 1.

The following objections/rejections of record are maintained or modified as follows:

The disclosure is objected to because of the following informalities: At page 1 7, citation of "U.S. Pat. No. 4,976,957 (S.N. 07/744,649)" is improper because the '957 Pat. issued from S.N. 07/281,883, not 07/744,649.

Appropriate correction is required.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of record is maintained. Contrary to applicant's urgings, the format of the claim does imply a genus-species relationship, since the claims call for stimulating the immune

system against malignin (line 2) and then recites 4 members which can be used to stimulate the anti-malignin response (lines 3-4). As far as applicant's urgings pertaining to the specification teachings are concerned, these arguments are unconvincing. Applicant has apparently referred to teachings in Example 8 that "The Recognin derivative vaccine can be any product larger, smaller or the same molecular weight which contains the immunological specificity of malignin, Recognin L or Recognin M". This is a statement about the nature of derivatives of the first 3 recited members of the Markush group of claims 1 and 5; since the last of the 3 members is set off by "or", it is not a statement that implies anything about these 3 members sharing any common "immunological specificity"/cross-reactivity. Further, since these specification teachings are referring to derivatives of all 3 of the members "malignin, Recognin L or Recognin M", claims 1 and 5 should be amended to clarify that such is what applicant intends; presently the claims are ambiguous as to whether the phrase "or a peptide having the immunological specificity thereof" refers to all 3 of the preceding, or only to the immediately preceding, Markush group member(s).

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1-5 recite new matter, as set forth at pages 6-7 of the previous office action. By way of clarification, it is noted that the new matter rejection should have been stated under the description requirement, rather than the enablement requirement, of 112, first paragraph.

Applicant has responded by showing exhibits of the original and the substitute abstracts from instant Ser. No. 09/854,568; these support the instant claims. However, the examiner had clearly required copies of the original abstract of parent case 08/031,562, so that its abstract could be compared with that instantly filed.; see previous action (pg 7, 1st para.).

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in

the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not teach those of ordinary skill in the art how to use the claimed invention without undue experimentation, for reasons of record.

Applicant's response to this rejection is that the material inserted that recites "which process does not by itself protect against or treat cancer" overcomes the rejection. This argument is unconvincing because all of the considerations presented by the BPAI during prosecution of parent case 08/031,562 (mailed 11/30/00 and 11/28/01) and reiterated in the previous office action (mailed 2/15/05) would be applicable, irrespective of whether the "stimulating of the immune system" is was intended to be fully effective by itself, or only efficacious when administered along with some additional treatment. It is to be noted that the term "treating" which was recited in the claims before the BPAI would encompass any effect, from a marginal inhibition of the cancer to a complete recovery therefrom; therefore it is not seen how the presently added limitations would overcome any of the conclusions reached by the BPAI.

It is further noted that applicant's disclosure is to be further considered non-enabling because of the addition of the new limitation that recites "which process does not by itself protect against or treat cancer". If one interprets "protect" or "treat" as did the BPAI, then undue experimentation would still be required to practice the invention as now claimed. There are numerous kinds of additional treatments which one might practice upon any cancer patient – for example, surgery, radiation or, chemotherapy. The latter of these, chemotherapy, can involve anyone of a vast number of different agents having different modes of effectiveness – for example, chemotherapeutic agents can variously induce apoptosis, inhibit cell division, or inhibit a receptor activation pathway. Applicant has not pointed out what type(s), among the vast number of other therapeutic agents/treatments, would be particularly efficacious in enhancing the protecting or treating effect of a malignin vaccine, which by itself would not protect or treat against cancer. Due to the vast number of other treatments that would need to be tried along with immunization against malignin, and due to the unpredictability of the art, undue experimentation would be required to practice applicant's invention.

The effective filing date for the claims is 3/15/93.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Bogoch (4,976,957), for reasons of record.

Claims 1-3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Bogoch (EP 0,015,078) for reasons of record.

Applicant has asserted that the claims are not directed to mere immunization of a subject for the purpose of producing antibodies. This argument is in error because the B-cells of any such immunized subject/animal would be stimulated to secret and release antibodies into humoral fluids. As far as the added limitation "which process does not by itself protect against or treat cancer" is concerned, this adds nothing to overcome the prior art. Any subject/animal being immunized for the purpose of obtaining anti-malignin antibodies as a biological reagent is not being immunized in order to "protect against" cancer, and it is not being immunized to "treat cancer"; thus the added limitation merely describes what is occurring, anyway, in the immunization methods of the prior art. There is nothing positively recited in the claim that requires that one be immunizing a subject/patient who has cancer or who has a propensity for developing cancer; likewise, there is nothing in the claim that positively requires that a subject/patient be also receiving some additional therapeutic treatment, such that it might be stated that the claimed process "by itself" does not prevent or treat cancer. Even if such a limit were to be added, it could be considered that an animal immunized for producing reagent antibodies would have inherently been "protected" against developing cancer. For the above reasons, it is proper for the examiner to reject over references showing merely immunization for the purpose of obtaining antibodies as biological reagents.

Claims 1 and 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bogoch (US '957 or EP '078) in view of Chase, for reasons of record.

Applicant's response to the 103 rejection of record has been merely to argue that the primary references have not been properly cited under 102. Since the 102 rejection has been maintained, the 103 rejection based thereupon has likewise been maintained.

Applicant's arguments filed 8/15/05 have been fully considered but they are not persuasive for the reasons above.

Applicant's amendment has necessitated the following new ground(s) of rejection.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 5 recite new matter.

In these claims the material inserted by amendment includes the limitation "which does not by itself". The examiner considers that this limitation is referring to a process or a composition which can administer or contain more than the anti-malignin antibody. The response of 8/15/05 has urged (pg 6) that "For example, at paragraph 8, Applicant teaches the use of Recognins in aid of other treatment"; however, the examiner finds that neither para. 8 nor any other para. referenced by applicant recites anything about any "other treatment". Applicant has also urged that para. 12 and 28 (does applicant mean 33?) refer to an augmentation effect in the treatment of cancer; however, the examiner does not find these teachings as referring to an "augmentation" of a treatment along with some "other treatment" but, rather, as referring to an augmentation of the naturally occurring level of anti-malignin antibody per se.

Further, even if the added limitation "which does not by itself" were not new matter in the literal sense, applicant would still not have been in possession of the claimed invention. As noted supra, regarding enablement, there are a vast number of different kinds of other cancer therapeutic agents/treatments, each of which is operative according to its own mechanism of action; therefore no one of the other kinds of possible cancer agents/treatments is representative of the whole genus of such agents/treatments. Applicant has not pointed out what type(s), among the vast number of other therapeutic agents/treatments, would be particularly efficacious in enhancing the protecting or treating effect of an immunization against malignin, which immunization by itself would not protect or treat against cancer. Due to the lack of any

disclosure in such direction, it is proper to reject the claims for lack of possession of the now claimed invention.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 2/4/05 DAS

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
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